

REMARKS**Status of the Claims**

Claims 13-37, 50-73, 87-110 and 112-189 are pending and at issue.

Double Patenting Rejection

Claims 13-37, 50-74, 87-189 stand rejected under the judicially created doctrine of obviousness-type double patenting over various claims of U.S. Patent Nos. 6,071,538, 5,714,167, and 6,348,207. Upon the finding of allowable subject matter, applicants agree to file a terminal disclaimer over these patents.

Applicants have previously agreed to file a terminal disclaimer over U.S. Patent No. 6,221,367 upon the finding of allowable subject matter.

Common Ownership of and § 103 rejection over U.S. Patent Nos. 6,071,538, 5,714,167, and 6,348,207

The Examiner has requested that Applicant's show common ownership at the time the invention in this application was made, or to name the prior inventor of the conflicting subject matter, with respect to the above-listed patents. The Examiner has also rejected claims 13-37, 50-74 and 87-189 as obvious over the above-listed patents.

Applicants note that these three U.S. Patents are parent applications to the present application, and they should not form the basis for an interference. See MPEP § 2301.01 ("An interference will not normally be instituted between cases that have a common assignee") and § 2302. Applicants are not aware of any error in inventorship in these patents, or the present application.

At the time the invention in this application was made, the application was owned by the same entity or subject to an obligation of assignment to the same entity, i.e., Emisphere

Technologies, Inc. See § 103(c). Upon the finding of allowable subject matter, applicants agree to submit a declaration under § 103(c).

Minor Informalities

Applicants thank the Examiner for pointing out that "reversibly" has been misspelled in the claims. Claims 13, 50 and 87 have been amended to correct the typographical error.

Rejections Under 35 U.S.C. § 103

Claims 13-16, 16, 23-25, 27, 32, 50-53, 55, 60-62, 64, 69, 87-90, 92, 97-99, 101, 106 and 112-189 stand rejected as obvious over Morishita (U.S. Patent No. 4,873,087) in view of Makino (U.S. Patent No. 4,746,675), or Makino alone.

Independent claims 13, 23, 50, 60, 87, 97, and 109, recite "exposing [a] biologically active agent to a complexing perturbant to reversibly transform [the] biologically active agent to [an] intermediate [conformational] state" (claims 13, 50, 87, 107) or "providing a biologically active agent in an intermediate conformational state non-covalently complexed with a complexing perturbant" (claims 23, 60, 97). Morishita and Makino do not explicitly disclose transforming or providing a biologically active agent in an intermediate conformational state. There is also no evidence in the cited references that the absorption promoters in Morishita, or the penetration enhancers of Makino necessarily provide a biologically active agent in an intermediate conformational state, and that such would be recognized by persons of ordinary skill. See MPEP § 2112 IV, *citing, In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999).

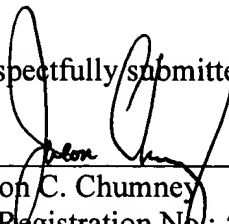
Furthermore, claims 13-16, 18, 23-25, 27, 32, and 138-163 relate to subcutaneous administration. The Examiner correctly notes that Morishita does not disclose subcutaneous administration. Makino discloses compositions for "external" administration, as specifically distinguished from administrations "to be injected into the body through an injection syringe", such as subcutaneous administration. (see Makino, col 1. lines 15-18). For the foregoing reasons,).

Morishita and Makino alone or in combination fail to render obvious the presently claimed invention, and applicants respectfully request that this rejection be withdrawn.

In view of the above amendment, applicant believes the pending application is in condition for allowance subject to the formal declarations and disclaimers mentioned above.

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Respectfully submitted,

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